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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte GENENTECH, INC.

Appeal 2009-004239
Application 10/606,745
Technology Center 1600

Decided: May 29, 2009

Before RICHARD E. SCHAFER, RICHARD TORCZON, and MICHAEL P. TIERNEY, *Administrative Patent Judges*.

TORCZON, *Administrative Patent Judge*.

DECISION ON APPEAL

The appellant, Genentech, seeks relief under 35 U.S.C. 134 from final rejections of claims 16, 28, 66, 67, 72, and 73.[1] We AFFIRM.

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[1] Examiner's Answer (Ans.) at 3. The answer also notes a formal rejection that is not appealed, but that is preferably cured when the claims are

INTRODUCTION

The examiner has rejected claims 16, 28, 66, 67, 72, and 73 "under 35 U.S.C. 103 as being estopped on the merits by final judgment in Interference No. 104,553." The examiner has rejected the same claims "under 35 U.S.C. 102(g) and/or 103 as being estopped on the merits by final judgment" in the same interference.[2] The interference is a related administrative proceeding.[3]

ISSUE

Does limitation of the contested claims to a method that predominantly affects glia make these claims patentably distinct from the subject matter of the claims that corresponded to the count of the interference [lost claims]?[4]

FINDINGS

[1] The application in this appeal is a reissue application for—[5]

P. Gluckman & K. Nikolics, IFG-1 to improve neural outcome, U.S. patent 5,714,460 (granted 3 Feb. 1998) [Gluckman patent].

[2] The Gluckman patent was the subject of an earlier interference.[6]

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otherwise allowable. *Id.* Hence, the contested rejection is not moot since the uncontested rejection will be cured if the contested rejection is reversed. Claims 64, 65, 68-71, and 74-77 are only subject to the uncontested rejection.

[2] *Id.* at 4.

[3] 37 C.F.R. § 41.8.

[4] *See In re Deckler*, 977 F.2d 1449, 1452 (Fed. Cir. 1992) (requiring focus on lost claims rather than lost count).

[5] Bibliographic data sheet; Reissue specification (Spec.), cover page.

[6] Intf. No. 104,553, Paper 111 (Decision on Motions) (Dec'n), at 1-2.

[3] Reissue claim 16, one of two contested independent claims, defines the invention as—[7]

> A method of treating glial cells damaged from CNS injury, wherein said CNS injury predominantly affects glia, comprising administering to the CNS of a mammal in need thereof, an effective amount of IGF-1.

[4] Glial cells (or glia) are cells of the central nervous system (CNS) that are not neurons, but are nevertheless necessary for normal central nervous system function.[8]

[5] IGF-1 abbreviates "insulin-like growth factor 1".[9]

[6] Genentech admits that "IGF-1 receptors are wide spread in the CNS…occurring on both glia…and neurons…."[10]

[7] Claim 28, the other contested independent claim, defines the invention as—

> A method of treating glial cells damaged from CNS injury, wherein said CNS injury predominantly affects glia, comprising administering to the CNS of a mammal in need thereof, an effective amount of a biological analog of IGF-1, wherein said analog is selected from the group consisting of naturally-occurring analogs, IGF-2, and des 1-3 IGF-1.

[8] Claims 66 and 72 further limit claims 16 and 28, respectively, by requiring that "said CNS injury is a demyelinating disorder."

[9] Claims 67 and 73 further limit claims 16 and 28, respectively, by requiring that "said CNS injury is multiple sclerosis."

[10] Multiple sclerosis is associated with loss of myelin.[11]

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[7] The language of the appealed claims is all reproduced from the claims appendix of the appeal brief (Br.).
[8] Spec. at 1:21-24 and 1:40-41.
[9] *Id.* at 1:11-18 (background).
[10] *Id.* at 2:55-59, citing prior art publications.

[11] Myelin is associated with glia cells.

[12] The count in the related interference was a "phantom" count comprising a claim from each involved patent and application, including claim 1 of the Gluckman patent.[12]

[13] Lost claim 1 of the Gluckman patent defined the following subject matter—[13]

> A method of treating neural damage suffered after a CNS insult affecting glia or other non-cholinergic cells in a mammal, comprising administering to the central nervous system of said mammal an effective amount of IGF-1 and/or a biologically active analogue of IGF-1.

[14] Claims 8 and 9 of the Gluckman patent depended from claim 1 and corresponded to the count, i.e., were claims lost as a result of the interference judgment.

[15] Claim 8 added the limitation that the CNS "injury is a consequence of multiple sclerosis."

[16] Claim 9 added the limitation that the CNS "injury is a consequence of a demyelinating disorder."

[17] Genentech uses "CNS insult" and "CNS injury" interchangeably since "injury" in the dependent claims would otherwise lack an antecedent.

[18] Lost claim 1 and independent appealed claims 16 and 28 all define a method of treating damage from a CNS injury affecting glia in a mammal by administering to the CNS an effective amount of IGF-1 or an IGF-1 analog.

[19] Claims 16 and 28 differ from lost claim 1 by referring to "neural damage" rather than glial-cell damage, by referring to "CNS injury" rather

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[11] *Id.* at 1:45-48 (background).
[12] Dec'n at 1.
[13] Dec'n at 2.

than "CNS insult", by eliminating express reference to CNS injuries affecting other non-cholinergic cells, by further restricting the CNS injury to one that "predominantly affects glia", and by selecting IGF-1 and its analogs, respectively.

[20] Claim 28 differs from lost claim 1 in requiring the analogs be naturally occurring and in permitting IGF-2 and a truncated IGF-1 as alternatives.

[21] Those skilled in the art were familiar with a broad range of CNS insults in man, including those involving damage to glia, and desired to prevent or reduce damage resulting from such insults.[14]

[22] Those skilled in the art were familiar with IGF-1, including its natural and synthetic production, its broad tissue distribution (including in human cerebral spinal fluid), and its broad metabolic activity.[15]

[23] Those skilled in the art knew that IGF-1 had neurological effects, including in the CNS and for glia.[16]

[24] Those skilled in the art knew that IGF-1 stimulates peripheral nerve regeneration.[17]

[25] Those skilled in the art knew that IGF-1 enhanced ornithine decarboxylase (ODC) activity in rat brains.[18]

[26] During the interference, ODC activity was found to be at least suggestive of improved neuronal survival.[19]

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[14] Spec. at 1:22-2:1, citing science journal articles and a CNS handbook.
[15] *Id.* at 2:6-39, citing science journal articles.
[16] *Id.* at 2:40-59, citing science journal articles.
[17] *Id.* at 3:5-7, citing a science journal article.
[18] *Id.* at 3:7-9, citing a patent issued to its interference opponent.
[19] Dec'n at 12-13.

[27] Genentech disclosed that it was not aware of anything in the art suggesting the use of IGF-1 "to prevent or treat CNS injury or disease leading to…loss of glia…in vivo."[20]

[28] Genentech has not provided evidence of secondary considerations, such as unexpected results.[21]

[29] Genentech has not pointed to a definition of "predominantly affects" in its specification.

[30] Judgment on priority as to count 1 was awarded against Gluckman in the interference.[22]

[31] Gluckman was adjudged not entitled to a patent containing claims 1-15 of the Gluckman patent.[23]

ANALYSIS

Claim construction

We focus on the contested limitations.[24] For claim 16, Genentech stresses that the CNS injury must predominantly affect glia.[25] In any case, the only other significant difference from lost claim 1 is that the treatment is directed to glial-cell damage rather than neural damage. The remaining differences appear to be simply variant wording or eliminated alternatives.[26] Similarly, for claim 28, Genentech relies on the added limitation that the

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[20] Spec. at 2:1-5.
[21] Br. at 36 (listing only the Gluckman patent as evidence).
[22] Intf. No. 104,553, Paper 116 (Judgment) at 2.
[23] *Id.*
[24] *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1256 (Fed. Cir. 2007).
[25] Br. at 9.
[26] *In re Johnston*, 435 F.3d 1381, 1384 (Fed. Cir. 2006) (optional elements not limiting).

CNS injury must predominantly affect glia. Claim 28 otherwise simply uses variant wording and both adds and eliminates some options. The other difference—that the IGF-1 analog be naturally occurring—is not presented as a patentable distinction.[27]

Since the dependent claims further limit the CNS injury to a demyelinating disorder or to multiple sclerosis, it follows that a CNS injury that predominantly affects glia must include demyelinating disorders, in particular, multiple sclerosis. The fact that a CNS injury *predominantly* affects glia does not exclude *some* effects on other cells or tissues, including neurons. Indeed, because glia support neurons, damage to glia is likely to affect neuron function as well. Genentech has not pointed to an express definition of "predominantly affects".

Interference estoppel

Precedent has identified at least four distinct types of interference estoppel.[28] The pertinent estoppels in this case are failure to distinguish patentably over the lost count (substantive), a type of estoppel by judgment, and estoppel for failure to file a motion (procedural).[29] Genentech notes that it could not have moved to add narrower claims that were patentably distinct from the count so it cannot be procedurally estopped for not having so moved.[30] Gluckman had, however, moved for judgment of no interference-

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[27] Br. at 13-14.
[28] *Woods v. Tsuchiya*, 754 F.2d 1571, 1579 (Fed. Cir. 1985).
[29] *Id.*
[30] Br. at 11, *citing L'Esperance v. Nishimoto*, 18 USPQ2d 1534, 1537 (BPAI 1991); *accord Winter v. Fujita*, 53 USPQ2d 1478, 1482 (BPAI 2000) (specifically noting that the procedure, subject to the limits of interference

in-fact[31] and for designation of claims 8 and 9 as not corresponding to the count,[32] but both motions were denied. Both of these denials provided basis for the judgment underlying the substantive estoppel. The subject matter of claims 8 and 9 have already been held to be patentably indistinct from the count, which included as an alternative the subject matter of lost claim 1.

The subject matter of claim 8 compared to appealed claims 67 and 73 shows the problem:

Claim 8/1	Claim 67/16	Claim 73/28
A method of treating neural damage suffered after a CNS insult affecting glia or other non-cholinergic cells in a mammal,	A method of treating glial cells damaged from CNS injury, wherein said CNS injury predominantly affects glia,	A method of treating glial cells damaged from CNS injury, wherein said CNS injury predominantly affects glia,
[wherein the central nervous system injury is a consequence of multiple sclerosis]	[wherein said CNS injury is multiple sclerosis]	[wherein said CNS injury is multiple sclerosis]
comprising administering to the central nervous system of said mammal an	comprising administering to the CNS of a mammal in need thereof, an	comprising administering to the CNS of a mammal in need thereof, an

estoppel, is to add the claim after the interference); see also Intf. No. 104,553, Paper 111 at 23 n.17.

[31] Dec'n at 19-24.

[32] Id. at 24-26.

effective amount of IGF-1 and/or a biologically active analogue of IGF-1.	effective amount of IGF-1.	effective amount of a biological analog of IGF-1, wherein said analog is selected from the group consisting of naturally-occurring analogs, IGF-2, and des 1-3 IGF-1.

In each case, a mammal with multiple sclerosis is treated by administering IGF-1 (or an analog) to its central nervous system. In short, the same step using the same compounds is directed to the same patients. Thus, a multiple sclerosis patient treated according to lost claim 8 would necessarily also be treated under appealed claim 67 (or claim 73 if an analog were used). Since multiple sclerosis is a demyelinating disorder of the central nervous system, the same analysis applies to the other appealed claims as well. Moreover, once administered, the IGF-1 cannot distinguish which cells it is treating or why it was administered. Thus, the method would treat both damaged neurons and damaged glia, regardless of which predominates.

Genentech's appealed claims recapture the very methods Gluckman lost in the interference judgment. Genentech is estopped from recapturing these methods. The rejection based on interference estoppel is AFFIRMED.

Obviousness

The obviousness analysis is effectively the same as the patentable-distinctness analysis. One skilled in the art and familiar with the subject

matter of the count would have known to treat neural damage in CNS insults affecting glia, including demyelinating disorders like multiple sclerosis, by administering IGF-1 or an analog. Since one would do so for an injury affecting glia it is reasonable to suppose one would still do so to treat neural damage even when the injury predominantly affects glia. In treating the neural damage, one would necessarily also be treating the predominant glial damage.

The case is perhaps clearest for the treatment of multiple sclerosis. Under either the count or the appealed claims, a multiple sclerosis patient would be treated by administering IGF-1 to the patient's central nervous system, thus treating both damaged nerves and glia. The broader claims are similarly obvious since obviousness of a dependent claim presumptively renders the broader claims obvious as well.[33] Genentech has not presented argument that would rebut the presumption.

While Genentech did not raise the issue, there is a legal issue regarding whether § 103 even applies to subject matter held to be a bar under § 102(g). Older precedent has held that § 102(g) does not provide "prior art" necessary under § 103 as a matter of statutory interpretation.[34] Section 103 has been amended to include express reference to situations in which § 102(e)-(g) are not prior art for the purposes of § 103.[35] For § 102(f), this amendment has been held to make "prior art" available under § 102(f)

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[33] *Aventis Pharma Deutschland GmbH v. Lupin, Ltd.*, 499 F.3d 1293, 1300 (Fed. Cir. 2007); *Ormco Corp. v. Align Tech., Inc.*, 498 F.3d 1307, 1319-20 (Fed. Cir. 2007); *In re Muchmore*, 433 F.2d 824, 824-25 (CCPA 1970).
[34] *E.g.*, *In re McKellin*, 529 F.2d 1324, 1327 (CCPA 1976).
[35] *See OddzOn Prods. v. Just Toys, Inc.*, 122 F.3d 1396, 1402 (Fed. Cir. 1997) (discussing amendment to § 103).

available for an obviousness analysis.[36] We see no principled reason not to extend the same reasoning to § 102(g).[37] Consequently, as a matter of law, subject matter that has been held to be unpatentable to an inventor under § 102(g)(1) is presumptively available under § 103 for analysis of claims the same inventor.

HOLDING

Claims 16, 28, 66, 67, 72, and 73 are not patentably distinct from the subject matter of the lost claims. In the alternative, the subject matter of the appealed claims would have been obvious in view of subject matter previously held to be unpatentable to Gluckman under § 102(g)(1). The contested rejection is—

AFFIRMED

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[36] *Id.*
[37] *Id.* ("Subsections (a), (b), (e), and (g) . . . are clearly prior art provisions.").